

Remarks

The Amendment enclosed herein addresses the claim rejections noted in the Office Action of 7/20/09.

With the present amendment, all previous claims have been canceled for the sake of clarity, and their content amended and presented in new claims.

New claims 51-88 amend the composition claims (1-37) of the original application, and claims 89-91 amend some of the method claims presented in the previous amendment.

Claim 52 is the amended claim 2 of the original application, and recites the several antimetabolites disclosed in the application with which the invention may be practiced. However, the Applicants had elected, with traverse, the antimetabolite of original claim 3 for examination in response to the restriction requirement of 7/29/05.

Hence, claim 52, which pertains to non-elected species has been indicated with the status identifier “withdrawn – new.”

Claims 38-44 had previously been withdrawn, with traverse, in response to the restriction requirement.

No new matter has been added by this amendment.

Claim Rejections – 35 USC Sec. 112

While maintaining the rejections of all claims for failing to comply with the written description requirement, the Office action depended on the examination of the claims as encompassing “a genus of oligonucleotides” (page 4); noted that the specification provides a number of oligonucleotide sequences (page 4); recognized the therapeutic potential of CpG oligonucleotides for immunotherapy (page 5); and stated that “claims are drawn to a vast genus of oligonucleotides” (page 6).

In rejecting all the claims as being indefinite for failing to particularly point out and distinctly claim the subject matter, the Office action issued new rejections necessitated by the previous amendment (page 9).

However the Office action also noted that despite the known properties of CpG oligonucleotides “the prior art appears to be silent on preferential killing of cancer cells over non-cancerous cells by CpG containing oligonucleotides or the structural requirements necessary for this function.” (Page 5).

In response, the Applicants state that whereas the use of CpG moieties for immuno-stimulation in the synthesis of oligonucleotides is well known in the art, this invention is the first to propose, and to demonstrate the effectiveness of, the use of nucleoside antimetabolites with CpG oligonucleotides for selectively killing cancerous cells over non-cancerous cells.

Thus, the functional component in the cancer-killing property of the oligonucleotides synthesized by the method of the present invention is based on the novel use of nucleoside antimetabolite employed, and not on the use of CpG *per se*, whose properties are already known in the art.

Furthermore, since the selective killing of cancerous cells over non-cancerous cells occurs from the novel use of a nucleoside antimetabolite (with known cancer-killing properties) covalently linked to an oligonucleotide with the CpG motifs, therefore this invention may be practiced with different antimetabolites in analogous manner.

The list of antimetabolites provided in the specification is known in the art and this list does not constitute the invention; but the use of associated nucleoside antimetabolites covalently linked to an oligonucleotide with the CpG motifs for the specific purpose of selectively killing cancerous cells over non-cancerous cells is part of the invention. The original claim 2 captured this novel use of the several antimetabolites.

Since the invention may be practiced analogously for the several antimetabolites, it is independent of the number of the antimetabolite “species.” Therefore, the number of “species” within the “genus” represented by the generic claim should not be at issue.

In response to the restriction requirement of 7/29/05, however, the Applicants had elected the “species” corresponding to claim 3 for further examination. Accordingly, the newly added claim 52 which recites the amended version of original claim 2 has been listed with the status identifier “withdrawn – new” pending further examination.

In addition to the these changes, the claim language now consistently uses the phrase "nucleoside antimetabolite," which is more precise and less confusing, in place of the word "prodrug."

CONCLUSION

The Applicants have addressed the matters raised in the Office Action of 7/20/09 and amended the claims in accordance with the guidance provided in the telephone interview with the Examiner.

The Applicants have shown that they had "possession" of the invention for fighting cancer as of the date of the application by disclosing an entirely new approach and by presenting compelling experimental data.

A Notice of Allowance is respectfully requested. You are requested to kindly contact the undersigned representative for any matter still outstanding in the case in order to put it into a condition for allowance.

Dated: September 21, 2009

Respectfully submitted,

*Suresh C. Srivastava, Satya P. Bajpai and
Kwok-Hung Sit
Applicants*

By: 

Indu M. Anand

Registration Number: 52,557

(978) 250-9003/ (617) 930-5000